

Case Study



Compliance Management

Abstract

Infosys Compliance Management Services help pharmaceutical companies address regulatory imperatives ranging from creation of error-free documents and reports to 21 CFR Part 11 compliance with Corrective and Preventive Action (CAPA). We combine robust knowledge of GxP and 21 CFR Part 11 compliance with rich implementation experience in system lifecycle development, system validation, and quality management.

Global Pharmaceutical Major Achieves Regulatory Compliance along with a Business Turnaround

A leading pharmaceutical company with interests in over-the-counter drugs, vaccines, diagnostics, and eye care wanted to upgrade its SAP 4.6 platform to ERP 6.0 across seven global system lines to accelerate innovation and grow business.

The company partnered with Infosys to upgrade its system while ensuring Good X Practice (GxP) and Sarbanes-Oxley(SOX) compliance. The SAP R/3 program was a mission-critical system for procurement, manufacturing, logistics, sales and finance, and reporting operations of the company.

We implemented the upgrade program with a multi-location team that tailored regional processes to the global strategy and methodology. Our holistic implementation covered -

- Quality management support
- Validation protocol and reporting, high-level risk assessment, functional risk assessment, and project document management
- Review and approval of key project deliverables

Business Benefits

Infosys helped the company achieve regulatory compliance while realizing several benefits -

- Testing and validation: The optimized system lifecycle and validation methodologies ensured data integrity
- Traceability: A zero defect process ensured efficient testing and implementation of GxP and SOX compliance, complete test coverage and establishment of mandatory core settings
- Compliance: The program reduced the cost of compliance by 40% while accelerating execution by 35%
- Risk mitigation: Our validation and compliance training programs ensured fast ramp up and consistent quality of compliance



For more information, contact askus@infosys.com

About Infosys

Many of the world's most successful organizations rely on Infosys to deliver measurable business value. Infosys provides business consulting, technology, engineering and outsourcing services to help clients in over 30 countries build tomorrow's enterprise.

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